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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/659,413 | 09/10/2003 | Peter Kite | 13317.1001cip | 4621 |
| 20601 | 7590 | 11/03/2004 | EXAMINER | |
| SPECKMAN LAW GROUP PLLC 1501 WESTERN AVE SEATTLE, WA 98101 | | | TRAVERS, RUSSELL S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,413

Applicant(s)

KITE ET AL.

Examiner

Russell Travers, J.D., Ph.D

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-52 is/are pending in the application.
- 4a) Of the above claim(s) 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

The amendment filed August 31, 2004 has been received and entered into the file.

Examiner notes two claims numbered "39" are presented in the amendment filed August 31, 2004. Examiner has renumbered, as per 37CFR 1.126, the second presented claim "39" as claim 40. Original claims 40-52 have been renumbered as claims 41-53. The presented action on the merits will reflect this new numbering schema.

Claims 32-53 are presented for examination.

During a telephone conversation with Ann Speckman on October 14, 2004 a provisional election was made without traverse to prosecute the invention of various EDTA compositions, claims 32-47. Affirmation of this election must be made by applicant in replying to this Office action. Claims 48-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 32-48 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 32-47 of copending Application No. 10/313,844. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36, 39-41 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Merck Index.

Merck Index teaches the instant claimed tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses. This compound is taught as an aqueous solution of 103 grams in 100 ml of water; yielding a 51.5% (w/v) solution, encompassing those solutions herein claimed. A 1% aqueous solution of this compound is taught as possessing a pH of 11, meeting those limitations herein recited. Examiner notes the

instant cited prior art fails to teach an antibacterial use for the instant claimed composition of matter recited by the Merck Index. Tetra-sodium EDTA would possess the herein recited benefits inherently, as a composition, and those benefits inherently residing in that composition are inseparable from those compounds contained in that composition.

Claims 32-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurginski.

Kurginski teaches the instant claimed tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses, in combination with alcohol, at a preferred pH of 10-11 (see page 8, paragraph 4). This EDTA compound is taught as an aqueous solution of ca. 0.25% to 15% (see page 6, paragraph 2), encompassing those solutions herein claimed. Claims 38 and 39 require an alcohol, wherein the composition contains less than 10% ethanol; attention is directed to claim 1 teaching compositions containing alcohols possessing 1-4 carbons at a concentration of 1-5%. Examiner notes the instant cited prior art exemplifies (example 1) an antibacterial use for the instant claimed EDTA/alcohol composition, wherein no ethanol is present, although an antibacterial use is taught for the compositions globally (page 3, paragraph 2). The skilled artisan would view the limitation of "less than 10% ethanol" as encompassed by no ethanol, as taught by example 1. Tetra-sodium EDTA in the Kurginski teaching is suspended in water and methanol, as required by the instant claims.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 32-43 and 45 are rejected under 35 U.S.C. § 103 as being unpatentable over Merck Index and Kurginski.

Merck Index teaches the instant claimed tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses. This compound is taught as an aqueous solution of 103 grams in 100 ml of water; yielding a 51.5% solution, encompassing those solutions herein claimed. A 1% aqueous solution of this compound is taught as possessing a pH of 11, meeting those limitations herein recited. Examiner notes the instant cited prior art fails to teach an antibacterial use for the instant claimed

composition of matter recited by the Merck Index. Tetra-sodium EDTA would as a composition inherently possess the claim recited benefits, with those benefits inherently residing in that composition taught in the prior art.

Kurginski teaches the instant claimed tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses in combination with alcohol, at a preferred pH of 10-11 (see page 8, paragraph 4). This EDTA compound is taught as an aqueous solution of ca. 0.25% to 15% (see page 6, paragraph 2), encompassing those solutions herein claimed. Claims 38 and 39 require an alcohol, wherein the composition contains less than 10% ethanol, Attention is directed to claim 1 teaching compositions containing alcohols possessing 1-4 carbons at a concentration of 1-5%. Examiner notes the instant cited prior art exemplifies an EDTA/alcohol mixture (example 1) wherein no ethanol is present, although an antibacterial use is taught for these compositions globally (page 3, paragraph 2). The skilled artisan would view the limitation of "less than 10% ethanol" as encompassed by no ethanol, as taught by example 1. Tetra-sodium EDTA in the Kurginski teaching is suspended in water and methanol, as required by the instant claims. As stated above, tetra-sodium EDTA would possess the recited antimicrobial benefits inherently, and those benefits would inherently reside in the Examiner cited prior art compositions. Claims 32-43 and 45, and the primary reference, differ as to:

- 1) employment of these medicaments to provide specific antimicrobial activity.

Examiner again reminds Applicants, the, tetra-sodium EDTA as set forth by the instant prior art would possess antimicrobial benefits inherently, and those benefits

would inherently reside in those prior art compositions herein recited. Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new. In the instant case, the presented claims simply recite an intended use for the instant old and well known ingredients, rendering these compositions obvious to those of normal skill in the art. Possessing the Kurginski teaching of broad spectrum anti-microbial activity, the skilled artisan would have been motivated to employ the claimed compositions as herein recited and enjoyed a reasonable expectation of success.

Claims 44 and 46-48 are rejected under 35 U.S.C. § 103 as being unpatentable over Merck Index and Cherepanov et al, in view of Remington's Pharmaceutical Sciences.

Merck Index teaches the instant claimed tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses. This compound is taught as an aqueous solution of 103 grams in 100 ml of water; yielding a 51.5% solution, encompassing those solutions herein claimed. A 1% aqueous solution of this compound is taught as possessing a pH of 11, meeting those limitations herein recited. Examiner notes the Merck Index fails to teach an antibacterial use for the instant claimed composition, although therapeutic uses are recited. Cherepanov et al teaches injected tetra-sodium EDTA as old, well known and useful for various pharmaceutical uses, to include diagnostic. Examiner notes Cherepanov et al employ the claimed tetra-sodium EDTA in

sheep by injection at a rate of 18 P.P.M.. Claims 44 and 46-48, and the primary references, differ as to:

- 1) recitation of intended use,
- 2) employment of these medicaments without pyrogens, and sterile,
- 3) employment of a pre-filled syringe, or vial, and
- 4) employment of saline carrier.

Applicant's attention is again drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new. In the instant case, the presented claims simply recite an intended use for the instant old and well known ingredients, rendering these compositions obvious to those of normal skill in the art. Possessing the Cherepanov et al teaching of injecting the claimed EDTA for diagnostic procedures, the skilled artisan would have been motivated to employ the claimed compositions without pyrogens, and with conventional sterile protocol as conventional with therapeutic regimens, and enjoyed a reasonable expectation of success. Examiner directs attention to Remington's Pharmaceutical Sciences, page 1837, column 1, paragraph 2, teaching hypodermic syringes as conventionally being 50 ml , or less. Possessing this teaching the skilled artisan would have been motivated to provide a syringe filed with an EDTA solution of 1%, or greater, for that diagnostic use recited by Cherepanov et al, and enjoy a reasonable expectation of success. The skilled artisan would see a pre-filled hypodermic syringe as a vial useful for multiple uses, absent information the contrary.

Cherenanov et al fail to recite a carrier for the diagnostic EDTA injection. Attention is directed to Remington's Pharmaceutical Sciences teaching saline solutions as ideal for injection. Examiner notes Remington's Pharmaceutical Sciences warns against injection of solutions containing pyrogens (see page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments. Possessing the Remington's Pharmaceutical Sciences teaching of injecting medicaments in the claimed saline carrier, free of EDTA for diagnostic procedures, the skilled artisan would have been motivated to employ the claimed compositions without pyrogens, and with sterile protocol as conventional with therapeutic regimens, and enjoyed a reasonable expectation of success.

Additional references are provided to illustrate the state of the art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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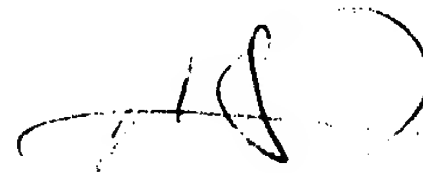
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Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617